

PATENT  
Attorney Docket No.: 50623.00067

**REMARKS**

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 40-48, 50-63, 78-81, 85-88, and 100-101 are pending.
- Claims 40-48, 50-63, 78-81, and 85-88 are rejected.
- Claims 64-77, 82-84, and 89-99 are withdrawn.
- Claims 100-101 are newly added.

Applicants have amended the specification to specifically include information that was previously incorporated by reference. For those paragraphs that are inserted into the specification, above, references to particular patents are provided. The text from these patents was incorporated by reference into the specification, as filed, according to the following paragraph. Because this material was previously incorporated by reference in the specification, as filed, explicitly adding it into the specification now does not constitute new matter. MPEP § 2163.07 (b).

U. S. Patent 5,069,899 was incorporated by reference in its entirety on page 4, line 29, of the specification. U. S. Patent 3,844,989 was cited in U. S. Patent 5,069,899 and therefore was incorporated by reference on page 4, line 50, of the specification. U. S. Patent 3,846,353 was cited in U. S. Patent 4,654,327 and therefore was incorporated by reference on page 4, line 50, of the specification. U. S. Patent 3,865,723 was cited in U. S. Patent 4,654,327 and therefore was incorporated by reference on page 4, line 50, of the specification. U. S. Patent 3,506,642 was cited in U. S. Patent 4,654,327 and therefore was incorporated by reference on page 4, line 50, of the specification. U. S. Patent 5,013,717 was incorporated by reference in its entirety on page 5, line 9, of the specification. U. S. Patent 5,322,659 was incorporated by reference in its entirety on page 5, line 9, of the specification.

The claims are amended as follows.

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Claims 53 and 58 have been amended to specify a polymer selected from the list of polymers as shown in the claims. Support for this amendment can be found in the specification as filed page 10, line 21.

Claims 60 has been amended to address the new matter rejection discussed below. Furthermore, step (d) has been rewritten -- purely a style change.

Claims 60 and 62 have been amended to recite that the applying step uses a solution containing a therapeutic drug and the adhesion enhancer. Support for this amendment is discussed below.

Claim 100 is newly added. Support for this claim can be found in claim 58 and in the second added specification paragraph. Support for that paragraph is discussed above.

Claim 101 is newly added. Support for this claim is found in the first and third added specification paragraph as and in the specification as filed page 10, lines 15-30.

#### 35 USC § 112

4. Claims 53-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and as being non-enabling due to the term "aromatic quaternary ammonium" being new matter.

The Examiner has an "initial burden of presenting evidence why a person having ordinary skill in the art would not recognize in [Applicants'] specification a description of the invention defined by the claims. Ex parte Sorenson, 3 USPQ2d 1462 (Bd. Pat. App. & Inter. 1987). Here, that means that the Examiner must present evidence why one of ordinary skill in the art would not recognize inventions drawn to "aromatic quaternary ammonium" ions in Applicants' specification. So far the Examiner has merely explained that the limitation "aromatic quaternary ammonium" is not explicitly present in the specification. But there is no in haec verba requirement for amendments. MPEP § 2163. The Examiner must present evidence why a person having ordinary skill in the art would

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not recognize that the term "aromatic quaternary ammonium" was not implicitly or inherently disclosed.

The specification explicitly recites several hundred or more aromatic-group-containing ammonium ions of all flavors. These aromatic-group-containing ammonium ions teach one of ordinary skill in the art the "aromatic quaternary ammonium" limitation. To the extent that the Examiner contends that the description of the specific ions somehow doesn't represent the entire breadth of "aromatic quaternary ammonium", the Examiner is invited to identify those flavors of aromatic quaternary ammonium ions that are missing from this description. While a subgenus is not necessarily described by a genus encompassing it and A species upon which it reads, here the genus is described along with SEVERAL HUNDRED species. MPEP § 2163. Applicants are not required to have literal support for the limitation "aromatic quaternary ammonium" in order to avoid a new matter rejection.

Incidentally, the Sorenson Board does not appear to be equating inherent disclosure with implicit disclosure. Specifically, the Board did not find that the disclosure explicitly recited "binuclear", nor did the Board find that this disclosure inherently recites "binuclear". Nonetheless, the Board found that the disclosure did teach the limitation. Even though not present explicitly or inherently, the Board had no trouble finding that the "disclosure reasonably convey[ed] to the skilled artisan that appellant had possession of the subject matter now claimed." , at 1464.

Please remove the new matter rejection identified above.

#### Paragraph 6

Claims 53-60, 40-48 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the claim(s) contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Regarding claims 60, 40-48, and 61, Applicants have deleted the word "polymeric", as the Examiner suggests. Applicants point out that the phrase "adhesion enhancer" in fact encompasses all polymeric adhesion enhancers.

Regarding claims 53-59, Applicants have amended the phrase to return it to its original form. "A copolymer of ethylene vinyl alcohol" does not exist because such a polymerization cannot be carried out. In fact, ethylene vinyl alcohol copolymers are prepared by polymerizing ethylene and vinyl acetate and then hydrolyzing the acetate groups off of the polymer chain, as is well-known to those of ordinary skill in the art. Applicants' position is that the recitation "ethylene vinyl alcohol copolymer" encompasses all such polymers, as would be recognized by those of ordinary skill in the art. Moreover, Applicants have added to these claims all polymers recited in the specification.

Please remove these rejections under 35 USC § 112

Paragraph 12

Claims 60-62, 50-51, and 78-80 are rejected under 35 USC § 102(b) as being anticipated by Onishi et al. (5,670,558).

As amended, claim 60 recites that "the step of applying comprises providing a solution comprising at least one therapeutic drug and the adhesion enhancer". Support for this amendment can be found in the specification at page 10, line 9, in which the specification teaches that the adhesion-enhancing substance is added to the heparin-containing compound, and the combination is then adhered to the surface.

With respect to claim 78, in its unamended form, it claims coating a surface with a formulation containing an adhesion enhancer and the heparin-containing compound.

The Examiner characterizes Onishi as teaching a method of coating an implantable device by applying a coating of heparin and ethylene vinyl alcohol copolymer. Paragraph 12 of the instant office action. But in column 12, Onishi teaches that the polymer solution contains an antithrombotic agent and a polymer capable of

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forming a surface lubricating layer. According to Onishi, the polymer capable of forming a surface lubricating layer is not selected from the list in column 8, as cited by the Examiner. Onishi speaks of two different types of polymers: the first type is referred to, in column 6, line 28, as "the water-soluble or water-swellaable polymer having reactive functional groups. . . "; the second type is referred to, in column 8, line 36, as "the polymer having a functional group capable of reacting with the reactive functional group in the first mentioned polymer. . . ". Then Onishi goes on to teach specific examples of the second polymer. It is the second polymer that can be an ethylene-vinyl alcohol copolymer. Therefore, Onishi does not teach a solution of a therapeutic drug and an adhesion enhancer, as is required by claims 60 and 78.

Since Onishi does not teach each and every element of the claims, it does not anticipate the claims. Therefore, please remove this rejection of claims 60 and 78 and their dependent claims -- 61, 62, 50-51, and 79-80.

#### Paragraph 13

The Examiner has rejected claims 60-62 and 78 under 35 USC § 102(e) as being anticipated by Goicoechea.

The Examiner cites column 4, line 45 and column 5, lines 5-11 as supporting that Goicoechea teaches a solution of polymer and heparin. Goicoechea teaches applying the polymeric material solution to a stent. Column 4, line 45. The solution is then dried to form a coating. Goicoechea then teaches that that coating may also incorporate certain drugs such as heparin. Column 5, line 4. This disclosure fails to teach that the drug and the polymer are both part of the same application solution.

Since Goicoechea fails to teach each and every element of these claims, please remove this rejection.

#### Paragraph 18

The Examiner has rejected claims 58-59 and 48 under 35 USC § 103(a) as being unpatentable over Onishi in view of Rowland et al.

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As discussed above, Onishi fails to teach a coating containing heparin and a polymer as listed in claim 58. Rowland does not cure this omission. Therefore, these combined references do not make claim 58 obvious. Claim 59 depend from claim 58 and is patentable for at least the same reason as claim 58. Claim 48 depends from claim 60 and is patentable for at least the same reason as claim 60.

Please remove this rejection.

Paragraph 19

The Examiner has rejected claims 53-57 under 35 USC § 103(a) as being unpatentable over Onishi in view of Rowland et al. and further in view of Hostettler.

As discussed above, Onishi fails to teach a coating containing heparin and a polymer as listed in claim 53. Neither Rowland nor Hostettler nor their combination cures this deficiency. Therefore, these combined references do not make claim 53 obvious. Claims 54-57 depend from claim 53 and are patentable for at least the same reasons as claim 53. Claim 48 depends from claim 60 and is patentable for at least the same reason as claim 60.

Paragraph 20

The Examiner has rejected claims 40-44, 52, 81, and 85-88 under 35 USC § 103(a) as being unpatentable over Onishi in view of Hostettler.

With respect to claims 40-44 and 52, these claims depend from claim 60 and are therefore patentable for at least the same reasons discussed above for claim 60. With respect to claims 81 and 85-88, these claims have limitation similar to those discussed above for claim 60, and therefore, the discussion for claim 60 applies to these claims, as well.

Please remove this rejection.

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Paragraph 21

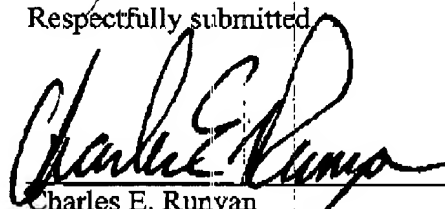
Claims 45-47 are rejected under 35 USC § 103(a) as being unpatentable over Onishi in view of Hostettler and further in view of Shah.

Claims 45-47 depend from claim 60 and are therefore patentable for at least the same reasons discussed above for claim 60.

Please remove this rejection.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted

  
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